Outpatient physiotherapy versus home-based rehabilitation for patients at risk of poor outcomes after knee arthroplasty: CORKA RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

CORKA RCT

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Scientific summary

Background

Knee osteoarthritis is a common musculoskeletal condition that causes pain and loss of function. It is the most common cause of disability in older people. Knee arthroplasty for end-stage osteoarthritis of the knee is an established and effective treatment for patients. The number of knee arthroplasty operations taking place in the UK is continuing to rise, as is the age of the patient and the American Society of Anesthesiologists classification grade, a method of categorising patients' fitness before surgery. Although most patients achieve a satisfactory outcome, many patients continue to report poor outcomes after knee arthroplasty. Given the rising number of these operations, the relatively limited therapy resources available and the increasing age and frailty of patients receiving joint arthroplasty, it is important to concentrate rehabilitation resources on those patients who need the most help to achieve a good outcome.

Objectives

The objectives of the COmmunity-based Rehabilitation after Knee Arthroplasty (CORKA) trial were to:

1. design a prognostic screening tool based on an analysis of factors associated with a poor outcome after knee arthroplasty to guide patient selection for the trial
2. evaluate whether or not a multicomponent rehabilitation programme delivered in patients' homes could improve their outcome compared with those receiving standard outpatient physiotherapy rehabilitation over 12 months
3. undertake a nested qualitative study exploring patients' and clinicians' perceptions of the community-based rehabilitation programme
4. undertake an economic analysis comparing the cost-effectiveness of the intervention with that of usual care.

It was hypothesised that the CORKA intervention would produce improved outcomes over usual care for participants identified as at risk using the CORKA screening tool.

Methods

The CORKA trial was a prospective, individually randomised, two-arm controlled trial with a blinded outcome assessment for the clinical outcomes at baseline, and at 6 and 12 (primary outcome) months. It aimed to determine whether or not a multicomponent rehabilitation programme that was provided to patients following knee arthroplasty who were deemed at risk of a poor outcome using the CORKA screening tool was better than usual care. The design included a parallel health economic evaluation and a nested qualitative study.

Setting

The trial was run in 14 NHS trusts across England.

Interventions

The CORKA home-based intervention

The CORKA home-based intervention was a multicomponent rehabilitation programme. Its aim was to improve the function and the participation in activities of participants at risk of a poor outcome after knee arthroplasty surgery. The primary component of the rehabilitation package was an individually adapted exercise programme conducted in participants' homes. Additional components consisted of functional task practice, appropriate adherence approaches and, if required, the provision of appropriate aids and equipment. The CORKA intervention started within 4 weeks of surgery. It comprised an initial assessment appointment and up to six follow-up sessions. It was delivered by a mixture of qualified staff and rehabilitation assistants.

Usual care

Those who were allocated to the usual-care arm received standard post-operative physiotherapy. Usual care after knee arthroplasty surgery could vary considerably across the trial's UK locations. However, it was highly likely that usual care would include several of the following: between one and six sessions of physiotherapy in an outpatient setting, class-based setting or hydrotherapy; written advice on home exercise at discharge from hospital; and an assessment of any potential home requirements for or barriers to discharge by an occupational therapist. To standardise usual care as much as possible, participants were expected to attend a minimum of one session and a maximum of six sessions of usual-care physiotherapy.

Recruitment

Patients were initially identified from clinic lists. Those who were scheduled to receive a knee arthroplasty were sent the CORKA participant invitation letter and participant information sheet. This pack was sent out by a member of the patient's usual-care team before they attended their pre-operative assessment clinic appointment. Patients who had been sent the information were approached during their pre-operative assessment clinic appointment to determine whether or not they were interested in the trial, and to give them the opportunity to discuss the trial further and ask any questions. If the patient indicated that they were interested in taking part, the CORKA screening tool was used to identify if they were at risk of a poor outcome. They were then checked for eligibility into the trial. If they were deemed eligible, an appointment was made to gain informed consent and to collect baseline outcome data with a member of the research team. This baseline appointment took place in the hospital or in the patient's home no more than 4 weeks before the date of the surgery. Patients were not formally recruited to the trial or randomised until their eligibility had been re-checked after surgery. Patients with serious peri-operative complications were excluded, as they would not be able to complete routine post-operative rehabilitation. Patients who were still eligible were then asked to confirm their consent verbally to a member of the research team before being enrolled in the trial and randomised.

Randomisation, allocation and blinding

Participants were randomly allocated by a computer-generated system to either 'usual care' or 'home-based exercise programme' in a 1 : 1 ratio. Randomisation used permuted blocks of various sizes (two, four and six) in a 1 : 2 : 1 ratio, and was stratified by recruitment site to account for any site effects. Participants and those delivering the rehabilitation were aware of the treatment allocation because of the nature of the intervention. Those carrying out follow-up outcome measurements remained blinded to treatment allocation.

Sample size

The primary outcome was the Late Life Function and Disability Instrument overall function score at 12 months. No information had been published about the minimum clinically important difference at the time of designing the trial, but it is a clinically relevant outcome in this population. The sample size calculation was based on a moderately small standardised effect size of 0.275. This standardised effect

size is, for example, equivalent to detecting a 3-point difference between treatment arms on the Late Life Function and Disability Instrument overall function score, assuming a standard deviation of 10.91 and no clustering effect across sites. In total, 620 participants (310 per arm) were required to detect a standardised effect size of 0.275 with 90% power and 5% (two-sided) significance, allowing for 10% loss to follow-up based on previous experience of trials in a similar population.

Monitoring and ethics

Trial oversight was provided by a Trial Steering Committee and an independent Data Monitoring Committee. The study protocol was approved by the South Central Research Ethics Committee (reference 15/SC/0019). Ethics permission was obtained for all participating sites.

Outcomes and analysis

Baseline data were collected face to face no more than 4 weeks before surgery. Follow-up data collection was carried out by face-to-face clinical assessments at 6 and 12 months following randomisation. Where face-to-face assessment was not possible, postal and telephone data collection methods were used to obtain self-reported core data.

Primary outcome

The Late Life Function and Disability Instrument was developed for community-dwelling older adults. It assesses and responds to meaningful change in two distinct outcomes: a person's ability to perform discrete actions or activities using a 32-item function component and a person's performance of socially defined life tasks using a 16-item disability component.

Secondary outcomes

Secondary outcomes consisted of self-reported and physical measures. The self-reported measures were the Oxford Knee Score, Physical Activity Scale for the Elderly questionnaire, Knee Injury and Osteoarthritis Outcome Score, Quality of Life subscale and EuroQol-5 Dimensions, five-level version. The physical measures were Figure-of-8 Walk Test, 30-Second Chair Stand Test and Single Leg Stance. A health resource diary collected the exercises undertaken, medication taken, use of health-care services and personnel, and falls.

Analysis

Two analysis populations were considered: the intention-to-treat population and the per-protocol population. The intention-to-treat population included all randomised participants who were analysed according to their allocated intervention. The per-protocol population included only participants who received at least one session of their allocated intervention, did not receive more treatment than intended (more than six sessions of usual care or seven sessions of home-based rehabilitation) and provided follow-up data.

The Late Life Function and Disability Instrument function scores at 6 and 12 months post randomisation were summarised by treatment group and analysed using a linear mixed-effects model with repeated measures adjusted for baseline score and recruitment site (stratification factor). Time was treated as categorical, and an interaction between the outcome measurement time point and the randomised group was included to allow the treatment effect to be estimated at each time point, reported as the adjusted mean difference in Late Life Function and Disability Instrument between groups with 95% confidence interval and associated *p*-value. The underlying assumptions of this model were assessed. The primary end point was considered to be 12 months post randomisation. The primary analysis was performed for the intention-to-treat population using multiple imputation to impute missing data.

Health economic evaluation

The CORKA home-based intervention and usual care were compared in terms of quality-adjusted life-years gained along with health and wider societal costs. Participants were asked to complete two diaries reporting their use of health-care services, time off work and any informal care received

because of their knee arthroplasty. The first diary ran between randomisation and 6 months, and the second between 6 and 12 months. Participants were also asked to complete the EuroQol-5 Dimensions, five-level version, questionnaire at randomisation (baseline), and at 6 and 12 months. Unit costs were derived from national databases, reports and websites. All unit costs were inflated, where necessary, to 2017–18 prices using the health-care and community health services inflation index.

Results

In total, 621 participants at 14 sites were randomised: 312 to usual care and 309 to the CORKA intervention. Most participants scored 5 or 6 on the screening tool (494/621, 79.5%) and received a total knee arthroplasty (460/621, 74.1%).

Primary outcome

The primary analysis of the Late Life Function and Disability Instrument function score demonstrated no statistically significant difference between the two treatment groups at the primary time point of 12 months (adjusted difference 0.49, 95% confidence interval −0.89 to 1.88; $p = 0.48$). There was also no statistically significant difference between the two groups at 6 months post randomisation or based on any of the sensitivity analyses.

Secondary outcome

No statistically significant differences between the two treatment groups at 6 or 12 months were identified for any of the secondary outcomes. Only one statistically significant difference was identified by the sensitivity analyses of key secondary patient-reported outcome measures for the Late Life Function and Disability Instrument disability limitation at 6 months using the intention-to-treat population and multiple imputation. This effect only just reached significance (adjusted difference 2.67, 95% confidence interval 0.14 to 5.19; $p = 0.04$), and is likely to have been a chance effect.

No significant differences between the two groups were identified on the physical measures 30-Second Chair Stand Test and Figure-of-8 Walk Test.

The health economic evaluation found a small, non-significant difference in quality-adjusted life-years (0.003, 95% confidence interval −0.017 to 0.023) favouring the CORKA home-based intervention. Post-operative physiotherapy (intervention) costs were lower, on average, in CORKA than usual care (−£65, 95% confidence interval −£86 to −£44). However, the CORKA group reported higher subsequent health-care resource use (primary care, outpatient care and hospitalisations) and costs (£142, 95% confidence interval −£70 to £354). The total NHS costs at 12 months were higher in the CORKA group (£77, 95% confidence interval −£138 to £291). By contrast, costs associated with private health-care use (−£15, 95% confidence interval −£76 to £46), informal care (−£23, 95% confidence interval −£210 to £164) and time away from paid employment (−£355, 95% confidence interval −£820 to £110) were lower for the CORKA group than for the usual-care group at 12 months. As a result, total societal costs (combining health-care costs and other costs) were lower for CORKA than usual care (−£316, 95% confidence interval −£892 to £260). Adopting an NHS health and social care perspective, CORKA compared with usual care was £28,372 per quality-adjusted life-year, close to the standard threshold for cost-effectiveness in the UK. Adopting a societal perspective, CORKA was cost-saving and more effective than usual care.

Qualitative study

As part of the main study, a nested qualitative study was conducted to obtain in-depth views about the intervention and how it was delivered. Ten patient participants, five physiotherapists and six

rehabilitation assistants were recruited. Semistructured interviews with participants were digitally audio-recorded and transcribed.

The themes related to physiotherapists and assistants were seeing the person in their world; developing people skills; thinking outside the cubicle; gaining personally from doing that bit extra; there is a fine line between patient and friend; feeling outside my comfort zone; and needing a support network. The themes related to patients were it was a relief not travel; I got an hour's work done in an hour; they can work with your surroundings; I didn't want to let them down; there is nothing like company; and I wouldn't have done it on my own.

Conclusions

The CORKA trial was a rigorous, well-conducted multicentre randomised controlled trial targeting a population at risk of a poor outcome following knee arthroplasty. This trial did not find an important difference between usual care and home-based rehabilitation in terms of Late Life Function and Disability Instrument function score at 12 months post randomisation. The key differences between the two interventions were that one was usual care, whereas the CORKA home-based intervention was multidisciplinary in content, delivered in participants' homes, and used a staffing model of rehabilitation assistants supervised by a qualified physiotherapist or occupational therapist. The data from the trial suggests that the two treatments are similarly effective and appear safe in this population.

Future research questions

It is suggested that further research should focus on developing a screening tool that is more sensitive to identifying those patients who will benefit from additional input. The CORKA screening tool was developed to identify the population most at risk of a poor outcome after knee arthroplasty but could be further developed to try to identify factors on an individual level or factors linked to engagement with rehabilitation.

The CORKA home-based intervention was delivered by rehabilitation assistants supervised by qualified therapists in a ratio of five sessions to two sessions. Considering these results in the context of workforce shortages across the NHS, further research to examine different workforce models and interventions solely using rehabilitation assistants could be explored.

Trial registration

This trial is registered as ISRCTN13517704.

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This report

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